



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Southwest Region

Food and Drug Administration  
Denver District Office  
Bldg. 20-Denver Federal Center  
P.O. Box 25087  
6<sup>th</sup> Avenue & Kipling Street  
Denver, Colorado 80225-0087  
Telephone: 303-236-3000

September 07, 2006

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Blair William McNea  
Whole Health Products, LLC  
37515 Highway 40  
Evergreen, Colorado 80439

Ref. No. CL-06-HFS-810-245

Dear Mr. McNea:

This is to advise you that the Food and Drug Administration (FDA) has reviewed your web site at the Internet address <http://www.wholehealthproducts.com> and has determined that the products "Alpha-Lipoic Acid," "Acetyl L Carnitine," "DMAE," and "L-Carnitine Fumarate" are promoted for conditions that cause the products to be drugs under section 201(g)(1) of the Federal Food, Drug, and Cosmetic Act (the Act) [21 U.S.C. § 321(g)(1)]. The therapeutic claims on your web site establish that the products are drugs because they are intended for use in the cure, mitigation, treatment, or prevention of disease. The marketing of these products with these claims violates the Act.

Examples of some of the claims observed on your web site include:

**Alpha-Lipoic Acid**

"Alpha Lipoic Acid is indicated by the German E Commission for adult onset diabetes."

"Alpha-lipoic acid has [sic] researched for use in the treatment of HIV and diabetes ...."

"I started taking Alpha Lipoic Acid two months ago, and am finally able to get feeling in my feet after 10 years of diabetic neuropathy!"

**Alpha Lipoic Acid and Diabetes**

Alpha Lipoic Acid is prescribed in Germany for adult onset of diabetes. There it has been shown to help for the following reasons:

- Alpha Lipoic Acid increases the sugar burning ability of insulin
- Alpha Lipoic Acid decreases insulin resistance
- Alpha Lipoic Acid increases ATP production

- Alpha Lipoic Acid decreases the symptoms of diabetic neuropathy  
Recommended supplementation for diabetic neuropathy is 800mg/day”

#### “Alpha Lipoic Acid and HIV?

....The benefits of Alpha Lipoic Acid in cases of HIV infection are touted on many websites, with little offered to back up the claim. ... Here is what we have found.

Michael Murray, ND, in his fine book, *Encyclopedia of Natural Medicine*, notes that 'Lipoic acid has antioxidant effects and is able to inhibit the replication of HIV by reducing the activity of reverse transcriptase-the enzyme responsible for manufacturing the virus from the DNA of lymphocytes. Based on these actions, it was suggested that lipoic acid might be of value in treating HIV-positive patients.' It is this quote that you will find cited in various places throughout the internet. Murray's claim is based on the following two studies, which a careful reading of his text clearly indicates: *A. Baur et al., Alpha lipoic acid is an effective inhibitor of human immuno-deficiency virus (HIV-1) replication, Klin Wochenschr 69 (1991): 722-4. Suzuki YJ Aggarwal BB Packer L, Alpha-lipoic acid is a potent inhibitor of NF-kappa B activation in human T cells. Biochem-Biophys-Res-Commun. 1992 Dec 30; 189(3): 1709-15 1992 0006-291X.* In addition to these citations, we have been able to find the following additional citations ...: *Merin JP Matsuyama M Kira T Baba M Okamoto T, Alpha-lipoic acid blocks HIV-1 LTR-dependent expression of hygromycin resistance in THP-1 stable transformants. FEBS-Lett. 1996 Sep 23; 394(1): 9-13 1996 0014-5793.*

*Grieb G, [Alpha-lipoic acid inhibits HIV replication]. Med Monatsschr Pharm 1992 Aug;15(8):243-4. (Article in German).*

Dr. Murray goes on to describe a follow-up study designed to test this hypothesis. The study yielded promising results. (that study: *Fuchs J Schofer H Milbradt R Freisleben HJ Buhl R Siems W Grune T, Studies on lipoate effects on blood redox state in human immunodeficiency virus infected patients. Arzneimittelforschung. 1993 Dec; 43(12): 1359-62 1993 0004-4172.*)

That is, to the best of our knowledge, the entirety of research on Alpha-Lipoic Acid and HIV. .... What the first three studies above indicate is that reactive oxygen species are implicated as signaling chemicals in the activation of NF-kappa B, which is required in HIV transcription. By blocking the activation of NF-kappa B, the transcription of HIV is subsequently stopped.”

#### Acetyl L Carnitine

“Studies have shown that Acetyl L-Carnitine benefits may include aiding your body's ability in fighting Alzheimer's disease, dementia and diabetes....”

“Acetyl-L-Carnitine is purported to help with a wide number of maladies. The best studied are:

- Alzheimer [sic] Disease, Dementia, Neuroprotection
- Geriatric Depression
- Diabetes and Diabetic Neuropathies”

[under the heading “Acetyl-L-Carnitine & Alzheimer's”]

“Many ...studies have shown that Acetyl-L-Carnitine can either slow the onset and progression of Alzheimer's Disease or it may alleviate some of the symptoms associated with Alzheimer's Disease. It is not precisely know [sic] why Acetyl-L-Carnitine seems to help with Alzheimer's Disease ...”

"[T]here are other possible ways that Acetyl-L-Carnitine may be helpful with Alzheimer's Disease. ... [W]e know that in individuals with Alzheimer's Disease, lipid and beta-amyloid plaques are formed on the brain. Beta-amyloid is an amino acid, the building blocks of proteins. It is believed that these plaques may be a cause of or co-factor in the development of Alzheimer's. There have been some studies that concluded that Acetyl-L-Carnitine can help reverse age related changes in lipid metabolism."

"Regarding geriatric depression, Acetyl-L-Carnitine seems to work in much the same way as it may with Alzheimer's Disease. Simply put, it may increase the levels of various neurotransmitters and thereby alleviate some of the symptoms of geriatric depression."

"It is as a transporter of long chain fatty acids that Acetyl-L-Carnitine may be beneficial to both Cardio function and Diabetic Neuropathies."

#### **DMAE**

"Research so far is not compelling, but the potentially positive impact has led people to use DMAE for Alzheimer's and/or senility ...."

#### **L-Carnitine Fumarate**

"L Carnitine seems to help people who have suffered congestive heart failure ...."

"L-Carnitine deficiency may also be implicated in diabetic cardiomyopathy, and seems to help people who have suffered congestive heart failure. L-Carnitine is well known to help in the treatment of angina pectoris, or heart pain (usually induced by physical stress)."

"L Carnitine deficiencies can also appear as ... angina (heart pain) ..."

Furthermore, your products are not generally recognized as safe and effective for the above referenced conditions and therefore, the products are also "new drugs" under section 201(p) of the Act [21 U.S.C. § 321(p)]. New drugs may not be legally marketed in the U.S. without prior **approval from FDA as described in section 505(a) of the Act [21 U.S.C. § 355(a)]**. FDA approves a new drug on the basis of scientific data submitted by a drug sponsor to demonstrate that the drug is safe and effective.

FDA is aware that Internet distributors may not know that the products they offer are regulated as drugs or that these drugs are not in compliance with the law. Many of these products may be legally marketed as dietary supplements if claims about diagnosis, cure, mitigation, treatment, or prevention are removed from the promotional materials and the products otherwise comply with all applicable provisions of the Act and FDA regulations.

Under the Act, as amended by the Dietary Supplement Health and Education Act, dietary supplements may be legally marketed with truthful and non-misleading claims to affect the structure or function of the body (structure/function claims), if certain requirements are met. However, claims that dietary supplements are intended to prevent, diagnose, mitigate, treat, or

cure disease (disease claims), excepting health claims authorized for use by FDA, cause the products to be drugs. The intended use of a product may be established through product labels and labeling, catalogs, brochures, audio and videotapes, Internet sites, or other circumstances surrounding the distribution of the product. FDA has published a final rule intended to clarify the distinction between structure/function claims and disease claims. This document is available on the Internet at <http://vm.cfsan.fda.gov/~lrd/fr000106.html>. The rule is codified under Title 21 of the Code of Federal Regulations (CFR) Part 101.93(g).

In addition, only products that are intended for ingestion may be lawfully marketed as dietary supplements. Topical products and products intended to enter the body directly through the skin or mucosal tissues, such as transdermal or sublingual products, are not dietary supplements. For these products, both disease and structure/function claims may cause them to be new drugs.

Certain over-the-counter drugs are not new drugs and may be legally marketed without prior approval from FDA. Additional information is available in Title 21 CFR Parts 310 and 330-358, which contain FDA's regulations on over-the-counter drugs.

This letter is not intended to be an all-inclusive review of your web site and products your firm markets. It is your responsibility to ensure that all products marketed by your firm comply with the Act and its implementing regulations.

If you need additional information or have questions concerning any products distributed through your web site, please contact FDA. Please send your written response to the Food and Drug Administration, P.O. Box 25087, Denver, Colorado, 80225-0087, Attention: Nancy G. Schmidt, Compliance Officer. If you have any questions concerning this letter, please contact Ms. Schmidt at (303) 236-3046.

Sincerely,



B. Belinda Collins  
Denver District Director

bcc: